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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,226	11/01/2006	Alastair Edwin McAuley	FPHCR.104NP	7568

20995 7590 03/30/2011
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EXAMINER

STUART, COLIN W

ART UNIT	PAPER NUMBER
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3771

NOTIFICATION DATE	DELIVERY MODE
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03/30/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/570,226	Applicant(s) MCAULEY ET AL.	
	Examiner COLIN STUART	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,8-12 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8-12 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment filed 12/7/10. As directed by the amendment, claims 1, 10, and 12 have been amended and claims 18-25 have been added. As such, claims 1, 3-4, 6, 8-12 and 18-25 are pending in the instant application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the removable outlet must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Note, it appears that the claims are directed towards the embodiment of the outlet vent shown in Fig. 8-12 as this is the only embodiment which includes the cover over a slot and in which the cover and the mask for an outlet vent which is a tapered slot with separation increasing from slot to edge of cover where gases exit. Fig. 8-12 do not give any indication of removability of this outlet member.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-4, 6, 8-12, and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunaratnam et al. (7,066,178) in view of Walker et al. (7,089,939).

In regards to claim 1, Gunaratnam shows a device for a supply of gases to a user which includes a mask 100, in use in fluid communication with a supply of gases and supplying the gases to a user (see Fig. 8 and col. 1 ln. 13-17 and col. 3 ln. 1-3), at least one outlet member in the form of a cover 114 integrated with or attached to the mask (see Fig. 8), wherein a boundary between the outlet member and the mask forms at least one narrow outlet vent (at 110 Fig. 8) that in use passes a substantial portion of expired gases of the user (see col. 7 ln. 45-48), wherein the outlet vent includes a slot formed in the mask (116 see Fig. 8) and a cover 114 extending over the slot and attached to the mask for diffusing the exhaled gases (see col. 7 ln. 45-48). Gunaratnam is silent as to a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent. However, Walker teaches a similar device which includes a cover and a mask forming an outlet vent wherein a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent (see Walker 138 Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Gunaratnam device's cover to extend such that a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent as taught by

Walker in order to increase the cross-sectional size of the outlet vent to decrease risk of occlusion.

In regards to claim 3, the modified Gunaratnam device's outlet member is removable (see Gunaratnam col. 7 ln. 36-37).

In regards to claim 4, the modified Gunaratnam device's at least one outlet vent is a substantially long tapered slot (see Gunaratnam Fig. 8 and Walker Fig. 8).

In regards to claim 6, the modified Gunaratnam device's at least one outlet vent extends between the top and bottom of the mask (see Gunaratnam Fig. 8).

In regards to claim 8 and 9, the modified Gunaratnam device discloses that the mask is a nasal mask or a full face mask (see Gunaratnam col. 5 ln. 15-19).

In regards to claim 10, Gunaratnam shows a CPAP system for delivering gases to a user (see 1 ln. 13-17) which includes a pressurized source of gases (col. 3 ln. 1-3), transport means in fluid communication with the pressurized source adapted to convey gases (see Fig. 8, tubing), and at least one removable outlet member in the form of a cover (114 see col. 7 ln. 36-37) integrated with or attached to the mask, wherein a boundary between the outlet member and the mask forms at least one narrow outlet vent that in use passes a substantial portion of expired gases of the user (col. 7 ln. 45-48), a slot formed in the mask (116) which the cover extends over to diffuse the exhaled gases. Gunaratnam is silent as to a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent. However, Walker teaches a similar device which includes a cover and a mask forming an outlet vent wherein a separation between the mask and the cover

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increases at a location between the slot and an edge of the cover where the gases exit the outlet vent (see Walker 138 Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Gunaratnam device's cover to extend such that a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent as taught by Walker in order to increase the cross-sectional size of the outlet vent to decrease risk of occlusion.

In regards to claim 11, the modified Gunaratnam device's outlet member is removable (Gunaratnam col. 7 ln. 36-37).

In regards to claim 12, Gunaratnam, Fig. 8, shows a removable outlet member (114 col. 7 ln. 36-37) for a gases delivery mask 100, in which the mask includes a slot 116 to which the outlet member, in the form of a cover 114, is provided on, and a boundary between the outlet member/cover and the mask forms at least one narrow outlet vent 110 that in use passes a substantial portion of expired gases from a user (col. 7 ln. 45-48). Gunaratnam is silent as to a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent. However, Walker teaches a similar device which includes a cover and a mask forming an outlet vent wherein a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent (see Walker 138 Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Gunaratnam device's cover to extend such that a separation between the mask and the cover

increases at a location between the slot and an edge of the cover where the gases exit the outlet vent as taught by Walker in order to increase the cross-sectional size of the outlet vent to decrease risk of occlusion.

In regards to claims 18, 22, and 24, the modified Gunaratnam device's separation between the mask and the cover increases to the edge of the cover (see Gunaratnam Fig. 8 and Walker Fig. 8).

In regards to claim 19, the modified Gunaratnam device's cover (Gunaratnam 114) includes a proximal end and a distal end, the proximal end located closer to the slot than the distal end (see Gunaratnam Fig. 8), wherein the separation between the mask and the cover increases from the proximal end to the distal end (see Gunaratnam Fig. 8 and Walker Fig. 8).

In regards to claims 20, 23, and 25, the modified Gunaratnam device appears to have an angle defined by the separation between the mask and the cover of between about 1 degree to about 20 degrees (see Fig. 8 of Walker). However, one of ordinary skill in the art at the time the invention was made would have found the angle as claimed to be an obvious matter of design choice; and furthermore one would expect the modified Gunaratnam device to perform equally as well with the claimed angle being between about 1 and 20 degrees.

In regards to claim 21, the modified Gunaratnam device includes a cross-sectional area between the mask and the cover which increases at a location between the slot and the edge of the cover along a direction towards the edge of the cover (see Gunaratnam Fig. 8 and Walker Fig. 8).

Response to Arguments

5. Applicant's arguments with respect to claims 1, 3-4, 6, 8-12, and 18-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771